

Remarks

Claims 18 and 19 have been added. Claims 1-19 are pending in the application. Claims 1-17 are rejected.

Claims 1-4, 6, 8, 9 and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by DiPietropolo (U.S. 4,741,922). The Examiner argues that DiPietropolo teaches all of the structures set forth in claim 1 because the instrument described is inherently capable of retaining an endotracheal tube. Applicant traverses the rejection.

DiPietropolo describes a flexible medullary reamer for shaping the medullary space of bones. Abstract. The shaft is comprised of a single, solid element. Abstract. To permit the use of an elongated guide element, the shaft may be axially bored throughout its length. Abstract. A cutting head and a means for connecting the shaft to a drive mechanism are connected to opposite ends of the shaft. Abstract.

Claims 1 and 17 are directed to an endotracheal tube retainer that comprises a solid, semi-rigid stylet rod having proximal and distal ends and a connection adapter that is tapered from a proximal end to a distal end for secure insertion within a range of endotracheal tubes. At least a portion of the adapter has an outer diameter in the range of about 2.0 mm to about 14.0 mm.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987); MPEP 2131. Here it is clear that each and every element of claims 1 and 17 are not set forth in DiPietropolo. Here, it is clear that DiPietropolo does not teach or suggest each and every element of either claims 1 or 17.

First, it is clear that DiPietropolo does not teach or suggest a connection adapter that is tapered from a proximal end to a distal end for secure insertion within a range of

endotracheal tubes. Rather, DiPietropolo teaches a medullary reamer for cutting through bones. What the Examiner refers to as a connection adapter is not a connection adapter at all. In fact, it is impossible for the device taught by DiPietropolo be used for that purpose. With reference to Figures 1 and 2 and col. 4, lines 35-40 of DiPietropolo, the cutting head taught is comprised of either stainless steel or tungsten carbide blades, which are carved diagonally around a head. The blades are specifically designed to cut through bone. The stainless steel or tungsten carbide is formed into blades so that when rotated by the means for connecting the shaft to the drive mechanism, the blades cut through the bone. The retainers of claims 1 and 17 comprise a connection adapter that is adapted to fit securely within a range of endotracheal tubes. During use, the adapter is inserted into the endotracheal tube that is to be removed such that the adapter is essentially lodged into the tube. When the adapter is removed, the endotracheal tube is retained within the oropharynx by the application of forward force, while the mask is removed by the user. The cutting head of DiPietropolo is not capable of accomplishing such. Endotracheal tubes are made of plastic. Accordingly, if the cutting head of DiPietropolo was inserted into an endotracheal tube it would clearly cut through the endotracheal tube, rendering it completely unusable. This would result in substantial risks to the patient relying on the endotracheal tube for respiration. Also, the cutting head would never fit securely within the tube as required by all of the claims because it would simply cut through the tube. Further, using the device of DiPietropolo in the manner suggested by the Examiner would result in damage to the laryngeal airway through which the endotracheal tube passes during the removal of the laryngeal airway. The stylet must traverse both the breathing tube and body portion of the laryngeal airway during the removal process of the laryngeal airway. If the blades of DiPietropolo were inserted, it would cause irreparable damage not only to the oral endotracheal tube, but to the laryngeal airway being removed. This is clearly undesirable and clearly the cutting head of DiPietropolo cannot be substituted for the connection adaptor of the claimed invention.

Therefore, the device of DiPietropolo clearly does not comprise each and every element of claims 1 and 17. The device taught by DiPietropolo simply is not designed or adapted to securely connect to an endotracheal tube, or anything else. Accordingly,

Application submits that claim 1 is not anticipated by DiPietropolo and respectfully requests that the rejection of claim 1 under 35 U.S.C. §102(b) be withdrawn.

Claims 2-4, 6, 8 and 9 depend from independent claim 1, and therefore incorporate all of the subject matter of claim 1. It is submitted that claim 1 is patentable over DiPietropolo because DiPietropolo lacks the claimed connection adapter. It is likewise submitted that claims 2-4, 6, 8 and 9 are patentable over DiPietropolo for the same reasons. Accordingly Applicant respectfully requests that the rejection of claims 2-4, 6, 8 and 9 under 35 U.S.C. §102(b) be withdrawn.

Claim 7 is rejected under 35 U.S.C. §103(a) as being unpatentable over DiPietropolo in view of Stone et al. (U.S. Pat. No. 5,525,316). Applicant traverses the rejection.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Claim 7 depends from claim 1, and therefore incorporates all of the subject matter therein. As such, it is clear for all of the reasons stated above that all of the claim limitations are not taught or suggested by the prior art by either DiPietropolo or Stone et al., singly or in combination. As stated above, neither DiPietropolo nor Stone et al. alone, or in combination, teach a retainer that comprises a connection adapter.

In addition, claim 7 is directed to a retainer that comprises a connection adapter that is composed of soft, semi-rigid material, sufficiently flexible to permit the connection adapter to traverse through an endo-tracheal tube after positioning within the oropharynx region. The Examiner asserts that "soft, semi-rigid" means that it is made of a material that would allow for the adapter to flex.

The Examiner's attention is directed to column 4, lines 35-40 of DiPietropolo where the use of tungsten carbide or stainless steel as the material of the cutting head is described. The Examiner's attention is also directed to Webster's Ninth New Collegiate

Dictionary where the term "soft" is defined as "yielding to physical pressure b : permitting someone or something to sink in – used of wet ground c (1) of a consistency that may be shaped or molded..." Clearly, neither tungsten carbide nor stainless steel is "soft" under the generally accepted meaning of the term, which the Examiner is required to interpret in its broadest sense.

Further, the connection adapter of claim 7 must be semi-rigid and "sufficiently flexible to permit said connection adapter to traverse through an endo-tracheal tube after positioning within the oropharynx region." Clearly neither tungsten carbide nor stainless steel is semi-rigid. Even if the blades of the cutting head would allow it to lodge within an endotracheal tube the nature of the tungsten carbide or stainless steel from which the cutting head is made would prevent movement of the cutting head through the tube. This is required by claim 7. The materials are simply too hard and rigid. The connection adapter of claim 7 must be comprised a material that allows it to move through an endotracheal tube. A material that is not soft and flexible will simply not accomplish the goals of the invention.

Further, obviousness can only be established when there is some teaching, suggestion, or motivation to combine the references found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Here, that motivation does not exist.

Moreover, there must be some reasonable expectation of success for the combination or modification. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986). There is no reason to believe that the modification proposed by the Examiner would be successful.

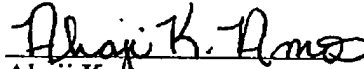
Therefore it is submitted that claim 7 is patentable over DiPietropolo and Stone et al. Accordingly, Applicant respectfully requests that the rejection of claim 7 under 35 U.S.C. §103(a) be withdrawn.

New claims 18 and 19 are submitted to be patentable for all of the reasons stated above.

Claims 10-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 107 of U.S. Patent No. 6,422,239. A terminal disclaimer in compliance with 37 C.F.R. §1.321(c) is included herewith to overcome the rejection.

Applicant believes that the arguments asserted and the amendments presented herein place all of the pending claims in condition for allowance. If the present amendments and arguments do not place the application in condition for allowance, the Examiner hereby requests an interview with the Examiner. It is respectfully requested that the Examiner contact the Applicant's undersigned attorney by telephone at (314) 872-8118 to schedule an interview.

Respectfully submitted,



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